Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents

October 14, 2011

Developed by the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents – A Working Group of the Office of AIDS Research Advisory Council (OARAC)

How to Cite the Adult and Adolescent Guidelines:

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It is emphasized that concepts relevant to HIV management evolve rapidly. The Panel has a mechanism to update recommendations on a regular basis, and the most recent information is available on the AIDS*info* Web site (http://aidsinfo.nih.gov).

access AIDS*info* mobile site

What's New in the Guidelines?

This revision to the January 10, 2011, guidelines is focused on **What to Start: Initial Combination Regimens for the Antiretroviral-Naive Patient**. Additions and key changes to the section are outlined below. More detailed discussion of the rationale for changes to the What to Start recommendations can be found in the updated section. Tables in the guidelines corresponding to the What to Start section have also been updated to reflect changes.

Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Based Regimens

- Rilpivirine added as an *alternative* NNRTI option for initial therapy in treatment-naive patients.
- All nevirapine-based regimens reclassified as *acceptable* options for treatment-naive patients (females with pretreatment CD4 count <250 cells/mm^3 or males with pretreatment CD4 count <400 cells/mm^3). Previously, "nevirapine + zidovudine/lamivudine" was classified as an *alternative regimen* and "nevirapine + abacavir/lamivudine" and "nevirapine + tenofovir/emtricitabine" were recommended as *regimens that may be acceptable but should be used with caution*.

Protease Inhibitor (PI)-Based Regimens

- "Ritonavir-boosted darunavir + abacavir/lamivudine" reclassified as an *alternative regimen* **(BIII)**; previously the regimen was recommended as a *regimen that may be acceptable but more definitive data are needed* **(CIII)**.
- Regimens with unboosted fosamprenavir removed as PI options for treatment-naive patients. The Panel removed the regimens because they have inferior potency compared with other PI-based regimens and because of the potential for selection of mutations that confer resistance to darunavir in patients who experience virologic failure while on these regimens.

Raltegravir-Based Regimens

- "Raltegravir + abacavir/lamivudine" reclassified as an *alternative regimen* **(BIII)**; previously, the regimen was classified as a *regimen that may be acceptable but more definitive data are needed* **(CIII)**.

Dual-Nucleoside Reverse Transcriptase Inhibitor (NRTI) Options

- "Zidovudine + lamivudine" reclassified from an *alternative* dual-NRTI option to an *acceptable* option because the combination has greater toxicities compared with tenofovir/emtricitabine and abacavir/lamivudine and requires twice daily dosing. However, zidovudine + lamivudine remains as the preferred dual-NRTI for pregnant women receiving antiretroviral therapy (ART) for prevention of perinatal transmission of HIV.
- "Didanosine + lamivudine" removed as a dual-NRTI option for initial therapy because the combination has the least clinical trial experience and greater toxicity compared with other available dual-NRTI options.
- Discussion on the association between abacavir use and the risk of a cardiovascular event updated.

In addition to the changes highlighted above, the following tables are updated with information relevant to rilpivirine:

- **Tables 14, 15b, and 16b** – Drug interaction tables
- **Appendix B, Table 2** – Drug characteristic table
- **Appendix B, Table 7** – Dosing recommendation for patients with renal or hepatic insufficiency